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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,292	04/02/1999	DONNA G. ALBERTSON	UCOTP089	3543
22798 7590 09/04/2008 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501				
EXAMINER				
HARRIS, ALANA M				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
09/04/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/285,292

Applicant(s)

ALBERTSON ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-17 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments and Arguments

1. Claims 1-12, 14-17 and 33 are pending.
Claims 1, 6, 9 and 11 have been amended.
Claim 33 has been added.
Claims 1-12, 14-17 and 33 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. The rejection of claims 1-12 and 14-17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' arguments.

New Grounds of Objection

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 1 cites "...the endogenous vitamin D 24 hydroxylase (CYP24) gene". There is no support in the specification for this newly amended claim.

New and Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12, 15-17 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER**

REJECTION. Applicants have amended independent claim 1 to include the recitation "...the endogenous vitamin D 24 hydroxylase (CYP24) gene" in section (ii) of the claim. Applicants have noted in their Remarks submitted May 29, 2008 that support can found on at least page 20, lines 12-14. The Examiner has reviewed this noted section and does not concur with Applicants. The Examiner has noted the term, endogenous in the paragraph bridging pages 49 and 50, however these citations do not support the contemplation of a method of detecting CYP24 nucleic acid or CYP24 protein encoded by endogenous vitamin D 24 hydroxylase. Applicants are requested to delete the new matter or point out support for the claim.

7. The rejection of claims 1-12, 14-17 and new claim 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made.

Applicants reiterate the criteria for meeting the written description requirement, as well as assert amending the claims to include the term "endogenous" precludes the instant rejection, see page 7 of the Remarks submitted May 29, 2008. Applicants aver the auxiliary verb, "can" does not preclude the *CYP24* gene from reading on wildtype, full-length *CYP24*. These points of view and arguments have been carefully considered, but found unpersuasive.

Amending the claims to include "endogenous" does not preclude the instant rejection because "endogenous *CYP24*" still encompasses a genus of molecules, such as nucleic acids, proteins and mRNA that are not necessarily wild type forms of *CYP24*. The term reads on a plethora of variant, mutated and alternate forms of *CYP24*. Applicants have not described *CYP24* with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. For the reasons of record and reiterated herein the rejection is maintained.

8. The rejection of claims 1-12, 14-17 and 33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting *CYP24* mRNA in human breast tumor *in vitro* specimens treated with 1,25-dihydroxyvitamin D-3 comprising RT-PCR, does not reasonably provide enablement for a method of detecting a predisposition to any cancer comprising detecting the level of *CYP24* nucleic acid or

Art Unit: 1643

CYP24 protein in a biological sample and comparing said level with the level from a control sample is maintained.

Applicants assert the Examiner's issue appears to be that "the claims read on prevention and forecasting" and Applicants' specification fully enables the pending claims, see page 8, last paragraph and page 9, last paragraph before the Conclusion section. Applicants point out to the Examiner breast cancer tumors, S1 and S59 and allude they are not established breast cancer cell lines, but breast cancer samples. Applicants' arguments have been carefully reviewed, but found unpersuasive.

The Examiner reiterates there is no doubt that one of ordinary skill in the art can detect CYP24 mRNA and protein levels, however Applicants' claims set forth if the target molecule is detected it should be readily presumed one will have breast cancer. While there may be data that confirms an association between CYP24 and breast cancer this does not necessarily denote the predilection for one to have breast cancer. The evidence in the specification does not support these claims. Hence, the specification is not commensurate with the scope of the claims. There is insufficient guidance in the specification providing methodology consistent with the claims. For the reasons of record and the reasons reiterated herein the rejection is maintained.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1643

10. Claims 1-12, 14-17 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 lacks antecedent bases for the recitation "...the endogenous vitamin D 24 hydroxylase...".

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

Art Unit: 1643

(571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.

20 August 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643